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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,194	10/31/2001	Reto Schoeb	015258-048710US	6423

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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,194	SCHOEB, RETO	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 70 is/are allowed.
- 6) ☒ Claim(s) 30-64, 68 and 69 is/are rejected.
- 7) ☒ Claim(s) 65-67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The substitute specification filed 12 March 2004 is acceptable and has been entered.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Note the first sentence of the substitute specification does not include a reference as discussed above.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 30-32, 36, 38-41, 49, 57, 60, 64 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Starkie et al.(WO 86/00636).

With respect to claims 30 and 57, the reference of Starkie et al. discloses a bioreactor device and method of use which includes using a flow of fluid to suspend the cells in the bioreactor chamber. The reference discloses that clumps of cells (tissue parts) are provided in the device (See page 4, lines 21-25). Fluid acts on the clumps of cells wherein the flow of the fluid is counter to gravity and the clumps of cells are held in free flotation (See the entire disclosure). In the absence of further positively recited claim language defining "tissue part", the clumps of cells are considered to meet this claim language.

With respect to claim 36, the reference discloses a bioreactor (1) including a container (2); at least one substance that can be clumps of cells (tissue parts) are provided in the device (See page 4, lines 21-25); and an apparatus for conveying fluid (3) so as to hold the substance in free flotation.

With respect to claims 31 and 64, the fluid has an increasingly lower flow speed in the direction counter to gravitation (See the abstract).

With respect to claims 32, 40, 60 and 68, the device includes fluid jet (3) for acting on the substance in the flow chamber.

With respect to claims 38, 39 and 41, the first flow chamber widens upwardly (See the abstract).

5. Claims 30, 31, 34, -36, 38-43, 45, 50, 51, 56-59, 62-64, 68 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Dean, Jr. et al.(US 4,978,616).

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The reference of Dean, Jr. et al. discloses device and method of use which includes a chamber (12); flow guiding means (14) which is positioned in the chamber so as to provide the required decreased flow with height; fluid conveying device (10) which includes an external motor and internal fluid conveying means (22-28). The device also includes oxygenation system (130) which introduces oxygen into a downward flow of fluid and introduced the gaseous media into the liquid media such that it is introduced with the upward flow of media into the flow chamber. With respect to the use of a "scaffold", the reference discloses the use of carrier beads which can be of a synthetic polymer for tissue culture (See column 4, lines 33-55). Note the instant specification defines a "scaffold" as a tissue carrier which can be a synthetic polymer. As a result, in the absence of further positively recited claim language to define "a scaffold" over the carrier beads of Dean, Jr. et al., the beads are considered to meet the instant claim language of "a scaffold".

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean, Jr. et al. (US 4,978,616) in view of Freedman et al.(US 5,501,971) and Schoeb et al.(US 6,100,618)

The reference of Dean, Jr. et al. has been discussed above.

The above claims differ by specifying the use of a magnetically driven rotor of a specific construction.

The reference of Freedman et al. discloses a bioreactor device with a draft-tube structure which includes a magnetically driven rotor so as to create a flow of fluid within the device (See Figure 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a magnetically driven impeller device in the system of the primary reference for the known and expected result of providing a means recognized in the art for creating a flow of fluid within a bioreactor device.

The reference of Schoeb et al. discloses a conventional rotary drive device which is employed for creating a flow of fluid within a housing or container. The rotary drive eliminates the need for bearing device and seals (See Figures 20 and 21).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the rotary drive device of the reference of Schoeb et al. to drive the impeller of the primary reference for the known and expected advantages associated with the design of the electromagnetic drive of the reference of Schoeb et al.

9. Claims 33, 37 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean, Jr. et al.(US 4,978,616). in view of Reh et al.(US 5,538,162).

The reference of Dean, Jr. et al. has been discussed above.

The above claims differ by reciting that the system includes a sensor and controller for controlling the flow of fluid in response to a position of the substance that is acted on by the flow of fluid.

The reference of Reh et al. discloses that it is known in the art to employ level sensors in the fluidized bed so as to control mass flow in the system (See sensors 15 and 12 in Figure 7 and claim 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary references with level sensors for the known and expected result of controlling the height of the fluidized material by controlling the flow of fluid in response to the detected height or level of the fluidized bed of material in the fluid flow zone.

Allowable Subject Matter

10. Claim 70 is allowed.
11. Claims 65-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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12. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 65-67 and 70, the prior art of record fails to teach or fairly suggest a bioreactor device that includes a first chamber and second chamber above the first chamber such that a fluid entering the bottom of the first chamber flowing upwardly has a lower speed with increasing height and a fluid entering the top of the second chamber flowing downwardly has a lower speed with respect to its distance from the top inlet.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 30-64, 68 and 69 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,632,658.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by claims 1-38 of U.S. Patent No. 6,632,658. Claims 1-38 of U.S. Patent No. 6,632,658 recite a scaffold having cells while the instant claims recite a substance that can be a tissue part, a scaffold having cells or a scaffold including a tissue part.

Response to Arguments

15. Applicant's arguments filed 12 March 2004 have been fully considered but they are not persuasive.

With respect to the obviousness-type double patenting rejection of record, applicant has indicated that a terminal disclaimer has been filed. However, a terminal disclaimer has not been received. It is also noted that applicant's transmittal form does not indicate that a terminal disclaimer was filed with the response dated 12 March 2004.

With respect to new independent claims 30, 36 and 57, applicant argues that these claims are allowable over the prior art of record because "none of the cited references, either alone or in combination, teach, disclose or even suggest such a bioreactor or method".

In response, Applicant's comments while generically stating that the newly presented claims define over the prior art of record in view of the claimed "substance" fail to set forth how the claimed substance differs from the tissue clumps and/or cells supported on a substrate as disclosed by the references of Starkie et al. and Dean, Jr. et al., respectively. In the absence for further positively recited claim language and/or convincing arguments, the Examiner is of the position that the cell clumps (tissue parts) and/or cells supported on a culture matrix meet the instant claim language in terms of the "substance" provided within the bioreactor chamber.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB